Hospital Reprocessors: Prepare for Your FDA Inspection

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- Hospitals reprocessing single-use devices (SUDs) must comply with all FDA requirements applicable to medical device manufacturers
- Compliance with applicable requirements will be verified through FDA inspection

Things You Will be Expected to Know

- The FDA policy governing the regulation of hospital reprocessors
- Whether FDA premarket clearances have been granted for reprocessed devices used in your hospital

You Will be Asked

- Are single-use devices being reprocessed within your hospital? If so,
  - Where?
  - What devices?
  - Has your hospital registered with FDA and listed devices being reprocessed?
  - Has your hospital taken steps to comply with both the premarket and postmarket requirements

Not Sure? Help is available.

- CD Rom: An Overview of the Regulatory Requirements for Reprocessing of Single-Use Devices by Hospitals
  - Request a free copy at: http://www.fda.gov/cdrh/reuse/reuse-important.shtml

Things You Can Expect

- Investigator will:
  - show FDA credentials upon arrival
  - request to see most responsible person at hospital
  - present a FDA 482 – Notice of Inspection
  - need to visit various areas throughout the hospital, e.g., receiving areas, supply rooms, sterilization areas

Items to Have Available

- Organization charts showing corporate structure, managers' names/positions held and areas of responsibility
- List of SUDs being reprocessed
- FDA premarket clearance letters issued to hospital

Items to Have Available
(continued)

- Copies of any policies dealing with reuse of devices intended for single use
- Reprocessing SOPs and records of reprocessing
- Copies of labeling for reprocessed devices

Conclusion of Inspection

- Investigator will:
  - discuss his/her inspectional findings
  - issue a FDA 483, if appropriate

If 483 Issued, FDA Suggests That Hospitals

- Respond by letter to FDA District Office to the FDA 483 observations
- Explain how hospital intends to make the necessary corrections
- Provide copies of any new operating procedures to implement corrections
- Give timeframe for completing corrections

Need Additional Information?

- Check the CDRH home page for available guidances and Questions & Answers

  www.fda.gov/cdrh/reuse/index.shtml

- Assistance available from:
  - Division of Small Manufacturers, International and
    Consumer Assistance
    OHIP/CDRH/FDA (HFZ-220)
    1350 Piccard Drive, Rockville, MD 20850
  - E-mail: DSMICA@CDRH.fda.gov
  - Telephone: 800-638-2041 or 301-443-6597